

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

**IN RE: NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION**

This Document Relates to:

Wray v. Ameridose, LLC, et al.

MDL No. 2419

Dkt. No 1:13-cv-12737

**PLAINTIFFS' REPLY TO THE STATE OF TENNESSEE'S MEMORANDUM OF LAW
IN SUPPORT OF TENN. CODE ANN. § 29-26-121(f)**

Plaintiffs respectfully submit this Reply to the State of Tennessee's Memorandum of Law in Support of Tenn. Code Ann. § 29-26-121(f). [MDL Dkt. No. 2654.]

First, setting the HIPAA preemption question aside, Defendants' motion can be denied here solely on the ground that Tenn. Code Ann. § 29-26-121(f) (hereinafter "121(f)") is a procedural discovery rule governing protective orders, and as such is in direct conflict with Fed. R. Civ. P. 26(c). Section 121(f) conflicts with Rule 26(c) because it affords the Court *less* discretion than does the federal rule in deciding whether to issue a protective order. As this Court has recognized, this impermissibly abrogates the federal court's discretion to manage the procedure and content of discovery, as well as guard against discovery abuses.¹ And because of this direct conflict between 121(f) and Rule 26(c), this Court must apply federal procedural law here. The State of Tennessee does not dispute this point. This alone is reason enough to deny Defendants' motion.

¹ See, e.g., *In re New England Compounding Pharmacy, Inc. Products Liab. Litig.*, No. MDL 13-02419-RWZ, 2014 WL 6676061, at *3 (D. Mass. Nov. 25, 2014) (finding state law discovery rule did not apply in federal court because it was a procedural statute that conflicted with the Federal Rules of Civil Procedure and thereby abrogated district court's discretion to manage discovery and administer sanctions).

That said, the State of Tennessee's argument is incorrect: HIPAA does preempt 121(f).

As explained more fully in Plaintiffs' Opposition [MDL Dkt. 2634], 121(f) is contrary to HIPAA because it "stands as an obstacle" to the accomplishment of Congress's "clear and manifest purpose" in enacting HIPAA to protect patients' rights to privacy and confidentiality of their medical information.

The express central purpose of HIPAA's Privacy Rule is "to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being."² At no point did Congress express any intent that HIPAA's provisions should benefit – or even take into account – a defendant's ability access to a plaintiff's protected health information in a lawsuit. Any entitlement a defendant has to a patient's protected health information comes through formal discovery mechanisms – written discovery and depositions – for which there are already established rules. There is no need to make up new rules. Consistent with Plaintiffs' proposal [see MDL Dkt. 2634-1], even in permitting informal discovery of Plaintiffs' treating physicians, this Court can ensure HIPAA's privacy-protective purpose remains inviolate by ordering that Plaintiffs' counsel be present at the treating doctors' interviews to supervise and protect Plaintiffs' rights and guard against the disclosure of irrelevant information in violation of HIPAA.

Tennessee argues that HIPAA does not preempt 121(f) because both laws provide the same protections for patient privacy "in the course of a judicial proceeding." But HIPAA contemplates judicial supervision of the disclosure of the *protected information* itself, to ensure

² "Summary of the HIPAA Privacy Rule," U.S. Department of Health & Human Services, available at <http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> (last accessed Feb. 15, 2016).

only the minimum necessary information is disclosed, while the only judicial supervision under 121(f) is in granting the protective order allowing the *ex parte* interview – and 121(f) is specifically set up such that it is practically impossible for the order not to be granted.³ An *ex parte* interview does not count as occurring “in a judicial proceeding” because “the trial court has no general oversight of the meeting or any control over it.”⁴ Requiring formal discovery procedures protects the court’s supervisory authority over the disclosure to ensure that all information discovered is within the permissible limits of the patient’s privacy rights, as well as the Rules of Civil Procedure.⁵

The State of Tennessee relies on two Tennessee district court opinions to support its argument; both are unpersuasive here. In *Lovelace v. Pediatric Anesthesiologists, P.A.*, the court

³ Contrary to Tennessee’s argument, the plaintiff’s “opportunity to seek to limit or prohibit an interview based on relevancy” under Section 121(f) is far less protective of patient privacy than HIPAA’s provisions. While it is true that 121(f) allows the plaintiff to object to defendant’s request for an *ex parte* interview, it only allows objection to the interview in its entirety, and only upon a showing that the doctor has *no* relevant information. In other words, where, as here, the treating doctor has both relevant and irrelevant information, a plaintiff has no recourse under 121(f) to successfully prevent the interview with her doctor, and is deprived of her right to object to “irrelevant inquiries” made during the interview itself and by so doing ensure her HIPAA-protected rights are not irreversibly violated. *See Alsip*, 197 S.W.3d at 728 (*citing Karsten v. McCray*, 157 Ill. App. 3d 1, 14 (App. Ct. 1987)). While HIPAA contemplates judicial supervision to protect these rights, under 121(f), the fox is guarding the henhouse: neither defense counsel nor the treating physician is in a position to decide what information is relevant, because the treating physician is not an attorney and is therefore not qualified to act as the arbiter of relevant information (or to ensure that s/he does not unwittingly violate HIPAA’s requirement that s/he disclose only the minimum amount of protected health information needed), and defense counsel cannot know in advance the substance of the information s/he seeks to elicit. *Roosevelt Hotel Ltd. P’ship v. Sweeney*, 394 N.W.2d 353, 357 (Iowa 1986) (prohibiting *ex parte* interviews prior to enactment of HIPAA: “We are concerned with the difficulty of determining whether a particular piece of information is relevant to the claim being litigated. Placing the burden of determining relevancy on an attorney, who does not know the nature of the confidential disclosure about to be elicited, is risky. Asking the physician, untrained in the law, to assume this burden is a greater gamble and is unfair to the physician. We believe this determination is better made in a setting in which counsel for each party is present and the court is available to settle disputes.”)

⁴ *State ex rel. Proctor v. Messina*, 320 S.W.3d 145, 152-55 (Mo. 2010).

⁵ *Id.*

correctly recognized that 121(f) is a procedural discovery rule,⁶ but failed to recognize that therefore under *Erie* the court was required to apply federal procedural law. The *Lovelace* court also failed to recognize (perhaps because the *Lovelace* plaintiffs failed to argue) that the “opportunity” to object provided by 121(f) is a far cry from the opportunity to object to inappropriate disclosure of a patient’s protected information that is afforded under HIPAA, and therefore 121(f) is contrary to HIPAA under the obstacle test. Tennessee’s other authority, *Wade v. Vabnick-Wener*⁷ (an earlier decision by the same court) is inapposite here, too, because it was decided before the enactment of 121(f) and therefore has no bearing on whether 121(f) is preempted by HIPAA.

For the reasons stated above and in Plaintiffs’ Opposition brief, Defendants’ motion should be denied. Alternatively, if the Court is inclined to grant the Defendants’ request for informal discovery interviews of Plaintiffs’ treating physicians, the Court should allow Plaintiffs’ counsel to be present at the interviews to protect Plaintiffs’ privacy rights. In what way could Defendants’ discovery aims be harmed or prejudiced by the presence of Plaintiffs’ counsel at such interviews?

⁶ No. 2:13-cv-02289-JPM-dkv (W.D. Tenn. Feb. 5, 2014) (“The ‘good cause’ and relevancy standards in Tenn. Code Ann. § 29-26-121(f) are consistent with the standards for discovery and issuance of protective orders under the Federal Rules of Civil Procedure...”).

⁷ 922. F. Supp. 2d 679, 690 (W.D. Tenn. July 2, 2010).

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Respectfully submitted:

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CERTIFICATE OF SERVICE

I, Annika K. Martin, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: February 15, 2016

/s/ Annika K. Martin